K073559

510(k) Summary

Submitter: Edwards Lifesciences Research Medical, Inc.

Contact Person: John W. Nicholson, Senior Regulatory Affairs Associate
6864 South 300 West
Midvale, UT 84047
801-565-6282

JAN 31 2008

Date Prepared: December 18, 2007

Trade Name: Edwards Lifesciences Arterial Perfusion Cannula II

Classification Name: Cardiovascular Diagnostic Devices, CFR 870.1300, Catheter Cannula, Product Code DQR, Class II

Predicate Device: Edwards Lifesciences Arterial Perfusion Cannula

Device Description: Edwards Arterial Perfusion Cannulae are polymeric tubes intended to provide a means of returning oxygenated blood to a patient during cardiopulmonary bypass procedures.

The cannulae are available in a range of sizes and types and in a variety of tip configurations. Some cannulae are reinforced by means of a stainless steel wire entirely encapsulated within the wall of the cannula to minimize the potential for cannula kinking and twisting; other cannulae are non-reinforced. Some cannulae are provided with a movable suture ring, a fixed suture ring or a fixed suture bump or flange to facilitate the fixation of the cannula.

The devices are provided sterile, they are non-pyrogenic and they are intended for single use only.

Intended Use: The Edwards Lifesciences Arterial Perfusion Cannula is indicated for arterial perfusion in the extracorporeal circuit for <6 hours. Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

Comparative Analysis: It has been demonstrated that the APC II arterial perfusion cannulae are comparable to the predicate devices in intended use, fundamental scientific technology, material type, principles of operation and functional performance evaluations.

Functional/Safety Testing: The functional data indicate that the subject devices perform in a substantially equivalent manner when compared with the predicate device.

Conclusion: The APC II arterial cannulae are substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Edwards Lifesciences Research Medical, Inc.
c/o Mr. John Nicholson
Senior Regulatory Affairs Associate
6864 South 300 West
Midvale, Utah 84047

Re: K073559
Arterial Perfusion Cannula II
Regulation Number: 21 CFR 870.1300
Regulation Name: Catheter cannula
Regulatory Class: Class II (two)
Product Code: DQR
Dated: January 24, 2008
Received: January 22, 2008

Dear Mr. Nicholson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5.

Indications for Use Statement

510(k) Number (if known): K073559

Device Name: Edwards Lifesciences Arterial Perfusion Cannula II

Indications for Use:

The Edwards Lifesciences Arterial Perfusion Cannulae II are indicated for arterial perfusion in the extracorporeal circuit for <6 hours. Cannulation site is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuchinich

ision Sign-Off)
sion of Cardiovascular Devices

0(k) Number K073559